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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,285

06/01/2005

Masahiro Ozaki

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22850

7590

07/23/2009

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

NOTIFICATION DATE

DELIVERY MODE

07/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/537,285	Applicant(s) OZAKI ET AL.	
	Examiner KATHERINE L. FERNANDEZ	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11 and 14-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-11 and 14-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/3/09;7/2/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6, 2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ozaki (US Patent No. 5,995,581).

Ozaki discloses a computer aided diagnosis system, comprising: a sick portion detecting device configured to detect a sick portion candidate based upon a simple X-ray image acquired by a first modality (column 5, lines 12-27; column 9, lines 33-64; column 7, lines 26-47; see Figures 8 and 6); and a correspondence displaying device configured to relate the position of the detected sick portion candidate to an X-ray CT

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image of a plurality of X-ray CT images acquired by a second modality different from the first modality, and to display the X-ray CT image having an axial face corresponding to a position of a selected mark that corresponds to the position of the sick portion candidate displayed on the simple X-ray image (column 9, lines 33-64; column 7, lines 26-47; column 4, lines 9-24; column 3, lines 28-36; see Figures 8 and 6).

4. Claims 7 and 14, 19-20, 23, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Oikawa et al. (US Patent No. 6,549,645).

Oikawa et al. disclose a computer aided diagnostic system, comprising: a sick portion detecting device configured to detect a sick portion candidate based upon an X-ray CT image acquired by one modality (column 1, lines 9-20; column 2, lines 19-29; column 3, lines 59-62; column 4, lines 46-52, referring to highlighted area corresponding to a tumor (i.e. sick portion)); an image transforming device configured to transform volume image data (i.e. stereoscopic image data) acquired by one modality into a digitally reconstructed radiograph (i.e. reconfigured image) using a selected viewpoint (column 4, lines 8-52); and a correspondence displaying device configured to relate the position of the sick portion candidate detected by the sick portion detecting device to the digitally reconstructed radiograph and to display the digitally reconstructed radiograph corresponding to a position of a selected mark (i.e. highlighted area of interest with color) that corresponds to the position of the sick portion candidate displayed on the X-ray CT image having an axial face (column 3, line 59-column 4, line 52).

Claim Rejections - 35 USC § 103

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (WO 02/43801) as cited by applicant in view of Wang '05 (US Patent No. 7,103,205).

Wang discloses a computer aided diagnostic system, comprising: a first sick portion detecting device configured to detect a first sick portion candidate based upon a simple X-ray image acquired by a first modality (pg. 20, lines 12-25); a second sick portion detecting device configured to detect a second sick portion candidate based upon a second image (i.e. ultrasound image) related to the same region of interest of the same subject acquired by a second modality different from the first modality (pg. 20, lines 12-25); and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices, wherein the detection result synthesizing device compares positions of marks respectively selected based upon the first and second sick portion candidates respectively displayed on the simple X-ray image and on the second image (i.e. ultrasound image) having an axial face (pg. 20, lines 12-25; pg. 16, lines 6-17). The disclose that the second image data is used in conjunction with x-ray mammogram data for a more thorough diagnosis as compared to x-ray mammogram data alone (pg. 9, lines 23-25). See Figures 12A. They further disclose a correspondence displaying device configured to relate the

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positions of a sick portion candidate detected by the first sick portion detecting device on an image analyzed by the second sick portion detecting device and to display it, at the same time, to relate the position of a sick portion candidate detected by the second sick portion detecting device on an image analyzed by the first sick portion detecting device and display it (pg. 14, lines 6-22; ; pg. 19, line 28-pg. 20, line 25; pg. 8, lines 3-12; see Figure 4). They further disclose that the correspondence displaying device is configured to display the following portion so that the portion can be identified in case the detection result synthesizing device judges that there is the portion detected as a sick portion candidate by only either of the first or second sick portion detecting device (pg. 19, line 28-pg. 20, line 25; pg. 14, lines 6-22; see Figure 4).

However, they do not specifically disclose that the second image is an X-ray CT image. Wang'05 disclose an adjunctive ultrasound mammography system and associated methods including an adjunctive ultrasound display system configured to allow flexible, intuitive, and interactive viewing of breast ultrasound information in a manner that complements x-ray mammogram viewing (column 3, lines 49-54). They disclose that one of ordinary skill in the art would be able to apply their apparatus in the context of computerized tomography (CT), wherein individual image slices generated from CT scans form images of the breast along planes parallel to a standardized x-ray mammogram view plane (i.e. axial face) (column 13, lines 25-46). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Wang to have the second image(i.e. ultrasound image) be an X-ray CT image, as taught by Wang '05, as CT images may be manipulated in the same manner

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as ultrasound images and provide additional structural information that would provide a more thorough diagnosis as compared to x-ray mammogram data alone (column 13, lines 25-46).

7. Claims 8, 15 and 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozaki (US Patent No. 5,995,581) in view of Aird et al. ("CT simulation for radiotherapy treatment planning", 2002).

Ozaki discloses a computer aided diagnosis system, comprising: a sick portion detecting device configured to detect a sick portion candidate based upon a simple X-ray image acquired by a first modality (column 5, lines 12-27; column 9, lines 33-64; column 7, lines 26-47; see Figures 8 and 6); and a correspondence displaying device configured to relate the position of the detected sick portion candidate to an X-ray CT image of a plurality of X-ray CT images acquired by a second modality different from the first modality, and to display the X-ray CT image having an axial face corresponding to a position of a selected mark that corresponds to the position of the sick portion candidate displayed on the simple X-ray image (column 9, lines 33-64; column 7, lines 26-47; column 4, lines 9-24; column 3, lines 28-36; see Figures 8 and 6).

However, they do not disclose an image transforming device configured to transform a volume image data acquired by one modality (i.e. CT) into a digitally reconstructed radiograph using a selected viewpoint (i.e. reconfigure an image based upon stereoscopic image data), or that the sick portion detecting device is configured to detect the sick portion candidate based upon the digitally reconstructed radiography.

Aird discloses a review on the place of CT simulation in radiotherapy planning (pg. 937,

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see Abstract). They disclose the use of digitally reconstructed radiographs (i.e. DDRs) in radiotherapy planning, wherein the DRR "traces rays from the X-ray source through a 3-dimensional model of the patient made up of voxels determined from CT scans" (pg. 938, left column, first paragraph). They disclose advantages of using DDRs vs. using conventional radiography, such as more information can be visualized than in conventional radiography, and that DRR is useful for checking margins and is superior to a conventional radiography, particularly if bone overlies the region of interest (pg. 938). They disclose that particular structures, such as a tumor volume, may be outlined on a DRR (pg. 939, right column, Section: Virtual simulator software; pg. 942, right column; see Figure 4). They further disclose that a reference slice plane can be selected on the DRR, and an X-ray CT image having an axial face corresponding to the selected reference slice plane can be displayed (see Figure 5b-c; pg. 944-946, Sections : Head and neck, Bronchus). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Ozaki to include an image transforming device configured to transform a volume image data acquired by one modality into a digitally reconstructed radiograph using a selected viewpoint and have the sick portion detecting device be configured to detect the sick portion candidate based upon the digitally reconstructed radiograph instead of on the simple X-ray image, as taught by Aird et al., as the digital reconstructed radiograph allows more information to be visualized than in a conventional radiograph, thus allowing sick portion candidates to be more accurately detected (pg. 938).

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8. Claims 9-11, 16-18, 25, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang as cited by applicant in view of Wang '05 and Aird et al.

Wang discloses a computer aided diagnostic system, comprising: a first sick portion detecting device configured to detect a first sick portion candidate based upon a simple X-ray image acquired by a first modality (pg. 20, lines 12-25); a second sick portion detecting device configured to detect a second sick portion candidate based upon a second image (i.e. ultrasound image) related to the same region of interest of the same subject acquired by a second modality different from the first modality (pg. 20, lines 12-25); and a detection result synthesizing device configured to compare the results of detection by the first and second sick portion detecting devices, wherein the detection result synthesizing device compares positions of marks respectively selected based upon the first and second sick portion candidates respectively displayed on the simple X-ray image and on the second image (i.e. ultrasound image) having an axial face (pg. 20, lines 12-25; pg. 16, lines 6-17). The disclose that the second image data is used in conjunction with x-ray mammogram data for a more thorough diagnosis as compared to x-ray mammogram data alone (pg. 9, lines 23-25). See Figures 12A. They further disclose a correspondence displaying device configured to relate the positions of a sick portion candidate detected by the first sick portion detecting device on an image analyzed by the second sick portion detecting device and to display it, at the same time, to relate the position of a sick portion candidate detected by the second sick portion detecting device on an image analyzed by the first sick portion detecting device and display it (pg. 14, lines 6-22; ; pg. 19, line 28-pg. 20, line 25; pg. 8, lines 3-

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12; see Figure 4). They further disclose that the correspondence displaying device is configured to display the following portion so that the portion can be identified in case the detection result synthesizing device judges that there is the portion detected as a sick portion candidate by only either of the first or second sick portion detecting device (pg. 19, line 28-pg. 20, line 25; pg. 14, lines 6-22; see Figure 4).

However, they do not specifically disclose that one of the images is a X-ray CT image or that their system further comprises an image transforming device configured to transform volume image data acquired by the one modality into a digitally reconstructed radiograph (i.e. reconfigured image) using a selected viewpoint and that a sick portion is detected based upon the digitally reconstructed radiograph. Wang'05 disclose an adjunctive ultrasound mammography system and associated methods including an adjunctive ultrasound display system configured to allow flexible, intuitive, and interactive viewing of breast ultrasound information in a manner that complements x-ray mammogram viewing (column 3, lines 49-54). They disclose that one of ordinary skill in the art would be able to apply their apparatus in the context of computerized tomography (CT), wherein individual image slices generated from CT scans form images of the breast along planes parallel to a standardized x-ray mammogram view plane (i.e. axial face) (column 13, lines 25-46). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Wang to have a sick portion detected based upon an X-ray CT image (i.e. instead of based upon an ultrasound image), as taught by Wang '05, as CT images may be manipulated in the same manner as ultrasound images and provide additional structural information that

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would provide a more thorough diagnosis as compared to x-ray mammogram data alone (column 13, lines 25-46).

Aird discloses a review on the place of CT simulation in radiotherapy planning (pg. 937, see Abstract). They disclose the use of digitally reconstructed radiographs (i.e. DDRs) in radiotherapy planning, wherein the DRR "traces rays from the X-ray source through a 3-dimensional model of the patient made up of voxels determined from CT scans" (pg. 938, left column, first paragraph). They disclose advantages of using DDRs vs. using conventional radiography, such as more information can be visualized than in conventional radiography, and that DRR is useful for checking margins and is superior to a conventional radiography, particularly if bone overlies the region of interest (pg. 938). They disclose that particular structures, such as a tumor volume, may be outlined on a DRR (pg. 939, right column, Section: Virtual simulator software; pg. 942, right column; see Figure 4). They further disclose that a reference slice plane can be selected on the DRR, and an X-ray CT image having an axial face corresponding to the selected reference slice plane can be displayed (see Figure 5b-c; pg. 944-946, Sections : Head and neck, Bronchus). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Wang in view of Wang '05 to include an image transforming device configured to transform a volume image data acquired by one modality into a digitally reconstructed radiograph using a selected viewpoint and have first sick portion detecting device be configured to detect the sick portion candidate based upon the digitally reconstructed radiograph instead of on the simple X-ray image, as taught by Aird et al., as the digital

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reconstructed radiograph allows more information to be visualized than in a conventional radiograph, thus allowing sick portion candidates to be more accurately detected (pg. 938).

9. Claims 29 and 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Wang'05 as applied to claims 2 and 22 above, and further in view of Uppaluri et al. (US Patent No. 7,295,691).

As discussed above, the above combined references meet the limitations of claim 2. However, they do not specifically disclose a correspondence displaying device configured to cause a mark displayed when a sick portion candidate is detected on only one image among the simple X-ray image and the X-ray CT image to be different from marks respectively displayed when the first and second sick portion candidates are detected on both images. Uppaluri et al. disclose a method and system for computer aided detection and diagnosis of dual energy or multiple energy Images, as well as of radiographic images, computed tomography images and tomosynthesis images. They disclose that their CAD system has the ability to display markers for computer detected (and possibly diagnosed) nodules on any of four images (i.e. radiograph images, etc.), wherein each CAD operation may be represented by a unique marker style (column 10, lines 1-19). Markers indicating the results of the CAD operations are superimposed on the image data (column 10, lines 37-40). Superimposed upon the image may be, for example, circles around suspicious lung nodule classified as having characteristics of malignancy, a square around the calcified lung nodules classified as benign, and an arrow pointing to the detected bone lesions (column 10, lines 43-47). This provides the

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reviewer with benefits of the information from the CAD operations on each image presented simultaneously for optimal review (column 10, lines 48-50). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have a correspondence displaying device configured to cause a mark displayed when a sick portion candidate is detected on only one image among the simple X-ray image and the X-ray CT image to be different from marks respectively displayed when the first and second sick portion candidates are detected on both images, as taught by Uppaluri et al., for optimal review of the sick portion candidates.

10. Claims 30-31 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Wang '05 and Aird et al. as applied to claims 9,16,25 and 28 above, and further in view of Uppaluri et al.

As discussed above, the above combined references meet the limitations of claims 9,16,25 and 28. However, they do not specifically disclose a correspondence displaying device configured to cause a mark displayed when a sick portion candidate is detected on only one image among the simple X-ray image and the X-ray CT image to be different from marks respectively displayed when the first and second sick portion candidates are detected on both images. Uppaluri et al. disclose a method and system for computer aided detection and diagnosis of dual energy or multiple energy Images, as well as of radiographic images, computed tomography images and tomosynthesis images. They disclose that their CAD system has the ability to display markers for computer detected (and possibly diagnosed) nodules on any of four images (i.e.

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radiograph images, etc.), wherein each CAD operation may be represented by a unique marker style (column 10, lines 1-19). Markers indicating the results of the CAD operations are superimposed on the image data (column 10, lines 37-40).

Superimposed upon the image may be, for example, circles around suspicious lung nodule classified as having characteristics of malignancy, a square around the calcified lung nodules classified as benign, and an arrow pointing to the detected bone lesions (column 10, lines 43-47). This provides the reviewer with benefits of the information from the CAD operations on each image presented simultaneously for optimal review (column 10, lines 48-50). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have a correspondence displaying device configured to cause a mark displayed when a sick portion candidate is detected on only one image among the simple X-ray image and the X-ray CT image to be different from marks respectively displayed when the first and second sick portion candidates are detected on both images, as taught by Uppaluri et al., for optimal review of the sick portion candidates.

Response to Arguments

11. Applicant's arguments with respect to claims 1-4,7-11,14-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768